This document is one of three the Implementation Work Group prepared in the course of developing specific recommendations for the FACDQ to consider. It is intended to be an informational document only. The recommendations are presented in a separate document.

How Do We Promulgate?

Once the rule is issued in Dec. 2009, what are the DL_{nat} and the QL_{nat} for uses purposes? Can it be the existing MDL and/or ML until amended through subsequent rulemaking using the new approach(es)? If not, then how does the program function without national benchmarks for some Part 136 methods? Even if we use the existing MDLs and MLs, many methods do not currently have MDLs and MLs. What if the most sensitive/appropriate methods do not have a DL_{nat} or QL_{nat} but a less sensitive/appropriate method does? **EPA** **These issues are covered below as well.**

- **Timeline to Implement FAC Recommendations:**

1. Dec. 2007 FACDQ consensus report on approach(es) and uses

   EPA
   - Confirmatory testing of consensus approach(es)
   - Begins rule-making process
   - Begins planning training/outreach activities

   States
   - Continue existing approaches for handling D/Q issues or begins to transition as the states choose

   Permittees
   - No change in permits unless states begin to react/transition

   Laboratories
   - No change unless states begin to react/transition

2. Dec. 2008 EPA proposes rule. Assuming a FACDQ recommendation that EPA accepts, propose to amend
   - ❖ Part 136 (Analytical Methods) to add new approach(es).
   - ❖ Part 122 (EPA Administered Permit Programs: The National Pollutant Discharge Elimination System) to add uses provisions.

   EPA
   - Takes comments and continues rulemaking accordingly
   - Conducts training/outreach for states, permittees, labs

   States
   - Comments on proposed EPA rules
   - Participates in EPA training/outreach
   - Continues existing approaches or transitions

- Begins planning if federal rules are implementable with or without state rules

Permittees

- Comments on proposed EPA rules
- Still no change in permits, unless…

Laboratories

- Comments on proposed EPArules
- Still no change unless…

3. Dec. 2009 Final rule. All DLs and QLs promulgated after this date would be required to use the new approach(es). All previously promulgated MDLs or MLs would still be valid unless re-promulgated using the new approach(es). Preamble to this final rule could contain guidance to stakeholders or it could be a separate document issued at the same time. Rules should contain dates by which entities need to have accomplished certain tasks

- ❖ Time lag for states to modify rules to fully implement regulations
- ❖ Time by which labs need to be fully using the new procedures

EPA

- EPA publishes final rule and announces effective date ( ) days before actual effective date
- Implements new rules or oversight of states where delegated
- Begins promulgation of National Quantitation Limits based on priority

States

- Begin implementing federal rules or begin state rule promulgation (if rules are necessary, it may take another year or two)
- May need to maintain duplicate system for methods/analytes with National QLs versus those without
- Plan training/outreach to permittees

Permittees

- Newly issued permits may specify procedures to be used to set DL and QL and other steps resulting from new rules
- Existing permits may be modified by states to contain new procedures
- Existing permits may automatically signal changes because of language that anticipates rule-making
- If state does not modify permits or have automatic change language in permits, some permits could go 5 years under the current requirements

Laboratories

- Begin using new procedure
- May need to maintain duplicate procedures or nomenclature

4. December 31, 2010 Date by which time labs must have generated QLs and Dls using the new procedure

5. December 31, 2011 Date by which time delegated states must have fully implemented procedures that comply with federal requirements

~~6. Timeline – Full implementation will take place over a number of years~~
- ~~Time till EPA is able to promulgate single and multi/inter lab procedures, Part 122 changes and any other regulation reference changes is estimated to take about 24 months.~~
- ~~Time for labs to bring switch from MDL to modified ACIL – with the rule noticing requirements of EPA promulgation, labs will have advance notice of when changes will likely officially take place.~~
- ~~Some states will need to change rules to formally incorporate what EPA promulgates. This could take another year or two or more.~~
- ~~Initially, there may be very few analytes that have national QLs. States may have to maintain two systems for dealing with this issue~~ **~~State~~**
- **~~Transition Time for labs from Old to New Procedure.~~** ~~One year?~~ **~~Lab~~**

~~7. We would also need to determine the implementation timing. That is when would the new 40 CFR, Part 136, Appendix B procedure take effect? Immediately, or after 90 days, or must State rules be changed first? If some States adopt the need procedure before others, the labs may be in an odd predicament of having two maintain and report two sets of estimates, depending upon the client. Also, when would the revised reporting for DMRs take effect?~~ **~~Ind~~**

- **What else needs to be Promulgated besides what's currently in the Uses Document and the Procedures for determining QLs and DLs?**

1. Currently 40 CFR Part 136 does not require the Appendix B D/Q procedure to be used by labs working on CWA programs (except in a footnote for a few methods). There should be a requirement to use the procedure inserted somewhere in Part 136**. States**

~~2. Most Appropriate (sensitive) Method Issues~~ **~~States~~**
- ~~Issue where a method has a National QL but the method is not the most appropriate. May need to change the Uses Document Recommendation 6.B. to apply to "…NPDES Permits and Compliance Uses When No National Quantitation Limit Exists or when the existing National Quantitation Limit is for a method that is not the most appropriate method.~~
  Already captured in Uses Document.

  ~~On the issue of Most Appropriate (Sensitive) Method - if we go with the language in green (on my version), and there is a more sensitive method with no QL Nat, would that result in a permittee not having to follow the calculation and reporting requirements in item 6.A.2 of the latest uses document even though there is a QL Nat. I don't necessarily disagree with that outcome, but we should be clear that there could be situations (many if a state were to set things up that way) where the QL Nat would be "moot" unless it performed well in different matrices, etc.~~ Ditto

3. State Flexibility **States**

- States have specific issues. One state may have situations that do not pertain elsewhere. There needs to be flexibility for individual states to run programs in ways that make sense for the situations they face.

4. How do you address existing methods that do not have MLs in Part 136? **States** – Do we grandfather in existing MLs as National Quantitation Limits?

May be the need to differentiate the "old" MDL from the "new "MDL", as well as the QL's. There are several reasons for making the distinction:

a) EPA should not mix the old DL/QL information with the DL/QL from the new procedure. In feeding the DL/QL information it is necessary that only data from the new procedure DL/QL be used to help determine/update a national table.
b) b) States will need to know this information in order to properly feed the EPA database. In addition, the states may need to know the "old" vs the "new" to understand why the permittee's limits may have changed or are different from other permits.
- c) Regulators (field staff & office staff) will need to understand why sample reports have potentially significant differing DL/QL's from laboratory to laboratory

➢ **Issues that are dependent on which alternative we recommend for generating National Quantitation Limits**

1. We should also state that Alternate Test Procedures (ATP's) will be required to use the new procedure(s) and meet (or be more sensitive) than existing DL/QL's
States

2. <u>Including national QLs in methods prior to promulgation could create logistical problems.</u>

Authority for issuing QLnats probably lies with EPA. How are third party method developers going to do this? New methods to be considered by EPA for approval in Part 136 could be required to include single and multilab QL/DL determined according to procedures recommended by the FACDQ. EPA could then use this information as the basis for QL nat. This would allow EPA flexibility to have a single QLnat by analyte as a threshold for reporting, if so desired, by examining single and multilab QLs for all methods for a given analyte.
RB: Requiring QLnats in a new method to be adopted at Part 136 could prove a serious barrier to the adoption of new methods. For example, none of the methods recently adopted in the Methods Update Rule would have been able to be included without very considerable additional expenditures **Lab**

3. <u>Promulgating QLnats by analyte and method could create confusion in situations where not all approved methods contain a QLnat.</u>

RB: This is especially true in the case where the method with the QLnat is not the most sensitive method **Lab**